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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,750	02/19/2004	Joseph P. Vacanti	MIT 6917 (CMCC 450) DIV	5014
23579	7590	07/01/2005	EXAMINER	
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 07/01/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/782,750

Applicant(s)

VACANTI ET AL.

Examiner

DAVID J. ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/19/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent support for "the valve". Claim 1 fails to positively define the valve as a structure. Claim 1 only defines a "cell-matrix construct" for use as a heart valve.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,5,8,9,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Yannas (4902289).

Yannas discloses a method for making a cell-matrix construct comprising implanting into an animal a fibrous matrix formed of a biocompatible, biodegradable polymer having seeded therein cells selected from the group of substances as claimed.

Claim 2, see column 2 of Yannas.

Claim 5 is directed to a construct that is seeded with smooth muscle cells and maybe formed into a valve. (Note, the "valve" is not positively claimed.)

Claim 8, the construct of Yannas exhibits strength, flexibility and pliability as broadly claimed since the construct has the properties of the tissue in which it replaces.

Claim 9, see column 4, lines 1+.

Claim 15/1,15/2/15/5,15/8,15/9 is directed to the construct.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12,13,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yannas (4902289) as applied to claim 1 above, and further in view of Yannas, et al (4505266).

Yannas is silent to the use of growth factors for increasing new tissue formation prior to cellular seeding. Yannas, et al teaches that the use of growth factors are capable of increasing the rate of cellular proliferation and that the modifying the surfaces of the construct prior to seeding with growth factors was known at the time of the invention thereof. It would have been obvious to one with ordinary skill in the art to increase the rate of cellular activities of Yannas with the use of growth factors as taught by Yannas, et al.

Claims 1-5,8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks (3514791) in view of Schmidt, et al (4520821), Mikos (5514378) or Griffith-Cima et al (5709854).

Sparks discloses a method for making a cell-matrix construct for use as a heart valve comprising implanting into an animal a fibrous matrix formed of a polymer that has been seeded with specific selected cells. Sparks fails to teach that the matrix is biodegradable. Schmidt, et al, Mikos and Griffith-Cima et al teach the use of biodegradable matrix which is designed to allow biological tissue ingrowth to form a structure before the matrix is completely bioabsorbed. To replace the non-absorbable mesh of Sparks with an absorbable matrix as taught by Schmidt, et al, Mikos or Griffith-Cima et al to allow for a degradable template for new tissue formation would have been obvious to one with ordinary skill in the art.

Claim 2, see cells disclosed by Sparks.

Claim 3, Sparks discloses the steps of culturing a matrix at a first site then transplanting the new tissue to a desired site.

Claim 4, one embodiment disclosed by Sparks is a heart valve.

Claim 5, see cells of sparks or Schmidt, et al.

Claim 8, the newly formed heart tissue of Sparks would inherently possess the strength, flexibility and/or pliability of the tissue it is to replace.

Claims 9 and 10, see materials disclosed by Schmidt, et al, Mikos or Griffith-Cima et al.

Claim 11, see Mikos.

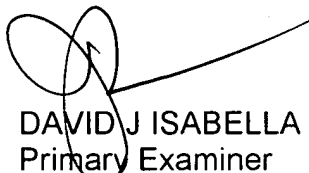
Claims 12-14, see Mikos or Griffith-Cima et al.

Claim 15, see construct of Sparks as modified by either of Schmidt, et al, Mikos or Griffith-Cima et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
June 22, 2005